IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, ex rel. BARRY ROSTHOLDER, ET AL.	:	
v.	:	Civil No. CCB-07-1283
OMNICARE, INC., ET AL.	:	

MEMORANDUM

Barry Rostholder ("Relator"), a former employee of Heartland Repack Services, LLC ("Heartland Repack"), brings this claim against Heartland Repack and its parent company, Omnicare Inc. ("Omnicare"), as a *qui tam* relator on behalf of the United States under the federal False Claims Act, 31 U.S.C. §3730(b)(1). Relator also includes claims under state and local false claims laws on behalf of 22 states; the District of Columbia; Cook County, Illinois; and the cities of Chicago and New York. Defendants Heartland Repack and Omnicare have jointly filed a motion to dismiss for lack of subject matter jurisdiction and for failure to meet the pleading standards of Fed. R. Civ. P. 9(b) and Fed. R. Civ. P. 12(b)(6). A hearing was held on June 28, 2012. For the following reasons, the defendants' motions to dismiss will be granted.

I. BACKGROUND

The federal False Claims Act ("FCA" or "the Act"), 31 U.S.C. §§ 3729–3733 (2006), prohibits persons and entities from knowingly presenting, or "caus[ing] to be presented," false or fraudulent claims to the federal government for payment or approval. *Id.* § 3729(a)(1). The FCA may be enforced directly by the Attorney General, but it also contains an alternative private

enforcement mechanism. This "*qui tam*" provision allows private individuals—often, but not always, whistleblowers with inside information about fraud—to bring suit on behalf of the United States. *See id*. §§ 3730(b), (e). The private individual, called a "relator," must file suit under seal, giving the United States government time to investigate the claim and choose to either intervene in the action or allow the relator to proceed on his own. *Id.* § 3730(b)(4). The action is then unsealed and notice provided to the defendant. If the action is successful, the relator receives a percentage of any proceeds. *Id.* § 3730(d).

This FCA case involves Medicare and Medicaid billing for Heartland Repack pharmaceutical products that may have been exposed to penicillin cross-contamination in violation of Food Drug and Cosmetics Act (FDCA) regulations. *See* 21 C.F.R. §§ 211.42(d), 211.176. According to relator, between 2001 and 2007[1] Heartland Repack sold the products to Omnicare pharmacies and other pharmacies jointly owned by Omnicare, knowing that the products were adulterated. These pharmacies then allegedly billed state Medicaid programs for reimbursement or resold the products to unrelated long-term care facilities which either directly or indirectly billed Medicare for the products. Relator argues that the United States and various states and localities did not get the benefit of the bargain when they reimbursed Omnicare and its clients for the allegedly adulterated products. Thus, relator argues, Heartland Repack and Omnicare should be liable under the federal False Claims Act and similar state and local laws.

A. Defendants' business model

[1] The False Claims Act contains a six-year statute of limitations, 31 U.S.C. § 3731(b)(1), which is tolled when the relator originally files suit. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 396 (D. Mass. 2007). Relator filed suit in 2007 and therefore this suit cannot reach any of defendants' actions that occurred prior to 2001.

Omnicare is a Delaware corporation with its principal place of business in Covington, Kentucky. The corporation provides pharmacy services to patients and residents of long-term care facilities. During the claim period, Omnicare operated approximately three hundred "long-term care pharmacies" that serviced skilled nursing facilities and long-term care facilities in forty-seven states. (Second Am. Compl. ¶ 67 ("SAC").) In 2006, the last year before this suit was filed, Omnicare reported $6.5 billion in net sales revenue. (*Id.* at ¶ 71.)

Heartland Repack is a wholly-owned subsidiary of Omnicare. In 1994, Omnicare entered into a 50-50 partnership with a long-term care provider, Health Care Resources, n/k/a HCR Manor Care ("HCR"), to form Heartland Healthcare Services. Heartland Healthcare Services was located in a warehouse in Toledo, Ohio, and was comprised of several units, including wholesale and distribution, repackaging, and a pharmacy. In 2001, Omnicare acquired HCR's ownership stake in the wholesale and distribution and repackaging units of Heartland Healthcare Services. With these units, Omnicare formed Heartland Repack.[2]

"Repackaging" was an important part of Omnicare's vertically-integrated business model. Most patients or residents of long-term care facilities are prescribed a regimen of various medications. Heartland Repack utilized a repackaging method through which the exact medications a patient needed at a certain time of day would be segregated into "sealed cells or 'blisters.'" (*Id*. at ¶¶ 73–75.) Heartland Repack would purchase bulk pharmaceutical products (mainly generic drugs) and then repackage them into "bingo cards" with plastic bubbles full of the appropriate medication or "unit doses" that were smaller versions of bingo cards. (*Id*. at ¶¶ 69, 76.) The repackaged drugs were sold to Omnicare's three hundred long-term care pharmacies as well as to the three Heartland Healthcare Services pharmacies. (*Id.* at ¶ 68.)

[2] In 2008, Heartland Repack was renamed Omnicare Distribution Center, LLC.

After the formation of Heartland Repack, the Heartland Healthcare Services pharmacy unit continued to be owned jointly by Omnicare and HCR, and the Heartland Repack repackaging unit and the Heartland Healthcare Services pharmacy unit continued to jointly occupy the original warehouse. (*Id.* at ¶ 61.)

Heartland Repack was a large facility. The company employed "over 100 individuals on a regular basis," (*id.* at ¶ 85), and by 2005 Heartland Repack was repackaging "over 200 million doses" annually. (*Id.* at ¶ 69.) According to relator, Heartland Repack was one of only two repackaging facilities owned by Omnicare, (*id.* at ¶ 72), with the other facility, Vanguard Repack, located in Glasgow, Kentucky. (Relator's Opp. to Def.'s Mot. Dismiss 25, ECF No. 87). At first, Heartland Repack was the larger of the two facilities, though they eventually became the same size "in later years." (SAC ¶ 72.) Heartland Repack and Vanguard Repack together provided a substantial percentage—or perhaps all—of the drugs for Omnicare's three hundred long-term care pharmacies.[3]

Reimbursement from Medicaid and Medicare has been an important source of sales revenue for Omnicare. According to Omnicare's 10-K filings with the SEC, as relator notes in the SAC, "historically approximately one half of [Omnicare's] revenue was derived 'directly from government sources, principally state Medicaid programs and to a lesser extent the federal Medicare program.'" (*Id.* at ¶ 70 (quoting Omnicare's Mar. 16, 2006, 10-K filing).) The SAC provides specific numbers from 2005 and 2006. In 2005, 46% of Omnicare's $5.3 billion in net

[3] Relator contends in his opposition memorandum that Omnicare's three hundred long-term care pharmacies received *all* of their drugs from either Vanguard Repack or Heartland Repack. (Relator's Opp. to Def.'s Mot. Dismiss 25, ECF No. 87.) This fact is not stated expressly in the complaint, but is implied by statements such as "[t]he repackaging operation provided repackaged pharmaceuticals to all of the Omnicare pharmacies," (SAC ¶ 85), and "at all times Heartland Repack was the source for a majority of the drugs that generated Omnicare's revenue, including revenue from government programs and plans." (*Id.* at ¶ 72.)

sales revenue was "derived from beneficiaries covered under state Medicaid programs." (*Id*.) After Medicare Part D became effective on January 1, 2006, the sources of Omnicare's revenue shifted toward Medicare. In 2006, 42% of the company's $6.5 billion in net sales came from Medicare and only 12% from Medicaid. (*Id.* at ¶ 71 (citing Omnicare's Mar. 1, 2007 10-K filing).)

The SAC provides a description of how the products were ordered from Heartland Repack and how government program reimbursement functioned. Heartland Repack would receive "an order for bingo cards or unit doses from an Omnicare [or presumably a Heartland Healthcare Services] pharmacy." (*Id*. at ¶ 77.) When the order was processed, Heartland Repack would "inscribe each bingo card or unit dose with a Lot Number, a Heartland Repack Services National Drug Code ("NDC") number, and the drug manufacturer's NDC number." (*Id*.) NDC numbers are unique three-segment numbers required by FDCA regulations.[4] The first segment of the number, the "labeler code," identifies the specific manufacturer or distributor (including repackers) of the drug product. *See* 21 C.F.R. § 207.35(b)(2)(i).

After repackaging, drugs were sent to Heartland Repack's wholesale and distribution unit, which "kept records of the drugs and lot numbers received." (SAC ¶ 78.) The wholesale and distribution unit then sold and shipped the products to the Omnicare and Heartland Healthcare Services pharmacies. These pharmacies "in turn provided repackaged drugs to HCR Manor Care Nursing Homes and other long-term care facilities." (*Id.* at ¶ 79.) As relator describes in the SAC:

[4] FDCA regulations require establishments "that engage in the manufacture, preparation, propagation, compounding, or processing" of human drugs to "register and submit a list of every drug in commercial distribution." 21 C.F.R. § 207.20. The drug lists must include NDC numbers for each drug. *Id.* § 207.25. The NDC number is "requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer." *Id.* § 201.2.

> Specifically, HCR Manor Care Nursing Homes and other SNFs/ALFs would submit patient pharmaceutical orders to their regional Heartland Healthcare Services or Omnicare pharmacy for processing. The orders would then be processed by the pharmacy intake department (which verifies all patient payor sources such as Medicare, Medicaid, private insurance, etc.), packed into a plastic "tote bag" for each patient, and shipped to the appropriate care facility.

(*Id.* at ¶ 80.)

Heartland Repack thus did not itself receive payments *directly* from government sources. The company's only income, as described by relator, came from sales of repackaged pharmaceuticals to Omnicare and Heartland Healthcare Services pharmacies. Whether and how government program reimbursement to these pharmacies took place depended on each patient, or the mix of patients, at a nursing home or SNF and their respective eligibility. Relator includes short descriptions of the various programs under which he alleges that the government provided reimbursements for Heartland Repack drugs.

Under Medicare, the Centers for Medicare and Medicaid Services ("CMS"), a division of the United States Department of Health and Human Services, provides reimbursements for the use of approved prescription drugs under the different relevant sections of the program. Medicare Part A uses a "Prospective Payment System" ("PPS") to pay for services provided to hospital inpatients, home health care patients, and patients of Skilled Nursing Facilities ("SNFs"). (*Id.* at ¶ 19.)[5] This system means that providers do not bill Medicare for specific drugs necessary for specific patients. Rather, as described in the SAC:

> [A] skilled nursing facility receives a "bundled" payment for all services and items provided to an SNF patient covered by Medicare Part A. The "bundled" payment is an estimate of the costs for all lodging, meals, skilled nursing care, physical therapy, medications, social services, and other qualified treatments

[5] Medicare will pay for care provided to SNF patients for up to 100 days, after which time the patient assumes responsibility for the costs. If the patient does not have the financial means to pay, then the costs are covered under Medicaid. (SAC ¶ 21.)

> based, in part, on actual cost data submitted by each SNF in its annual Cost Report.

(*Id.* at ¶ 20.) In annual Medicare Cost Reports, a facility would report the price it paid for drugs purchased from an Omnicare or Heartland Healthcare Services pharmacy. (*Id.* at ¶ 81.) And the facility "must properly differentiate between 'allowable costs' and 'non-allowable costs' incurred. Allowable costs include FDA-approved drugs, but not drugs whose safety was uncertain and therefore not in their FDA-approved form." (*Id.* at ¶ 20.)

After January 1, 2006, Medicare beneficiaries could enroll in Medicare Part D, which provided much broader prescription drug coverage than previously available under Medicare Part A. Part D is mediated by private insurers, called Part D Providers ("PDPs"). Under Part D, long term care facilities and skilled nursing facilities would order prescriptions from Omnicare or Heartland Healthcare Services pharmacies, and the pharmacies would bill PDPs. (*Id*. at ¶ 83.) PDPs receive payment from Medicare in accordance with previously negotiated agreements. As the SAC describes:

> [T]he government advances funds to the Part D Provider ("PDP") on a monthly basis according to the PDP's accepted bid. As an express condition of payment under Medicare Part D, for each prescription dispensed to one of its Part D enrollees, the PDP must submit to Medicare certain "prescription drug event data," including the price paid by the PDP. The required data is used in the year-end reconciliation process designed to ensure that the government ultimately only pays for the actual cost of FDA-approved drugs dispensed to enrolled beneficiaries.

(*Id.* at ¶ 26.)

Medicare Part C, also known as Medicare Advantage ("MA"), works through a similar model. Part C allows Medicare beneficiaries to receive all Medicare benefits (not just for prescription drugs) through private insurance plans, instead of directly from CMS. Under MA,

the government pays the private insurer a monthly amount per enrolled beneficiary. (*Id.* at ¶ 23.) MA plans cover the costs associated with Medicare Part A, and for an additional premium MA plans may also offer Medicare Part D outpatient drug coverage—these are known as MA-PD plans. For drugs provided to beneficiaries with either type of MA plan, Omnicare or Heartland Healthcare Services pharmacies would bill the private Part C providers who "in turn received funds from the government," (*id.* at ¶ 83), and "the government imposes certain reporting requirements to ensure that it is only paying for eligible drugs." (*Id.* at ¶ 23.)

Under Medicaid, which is a joint federal-state program, the Omnicare and Heartland Healthcare Services pharmacies "submit claims directly to the relevant state Medicaid agency's fiscal intermediary, which then pays the claims according to that state's approved Medicaid covered drug payment schedule." (*Id.* at ¶ 29.) Federal laws and regulations limit Medicaid payments to those for "reasonable and necessary services." (*Id.* at ¶ 30.) And coverage of outpatient drugs is limited to "those that meet all the requirements and conditions of FDA-approval." (*Id.* (citing 42 U.S.C. § 1396r-8(k)(2)(A)(i)).) The federal government makes quarterly grants to each state to reimburse the state for the federal share of Medicaid expenditures. *See* 42 C.F.R. § 430.30. To obtain reimbursement for the federal share of program expenditures, a State must submit a quarterly expenditure report to CMS (the "CMS–64 Report") stating the amount the State expended on services during the relevant quarter. *Id.*

Relator also alleges that drugs repackaged at Heartland Repack were, in some cases, eventually reimbursed by federal programs other than Medicare or Medicaid. The SAC briefly describes and provides citations to the laws and regulations governing the TRICARE/CHAMPVA program for active duty and retired members of the uniformed services,

the Veteran's Health Administration, and the Federal Employee Health Benefit Program. The SAC, however, does not provide any factual allegations to support the claim that beneficiaries of those programs were served with drugs repackaged at Heartland Repack. Thus, it is unnecessary here to detail the specific reimbursement policies and procedures of these programs.

B. Relator's allegations of fraudulent conduct

Relator began his employment for the defendants in 1997 and left in February or March of 2006. At some point during this time period, and presumably during the events described below, he was employed by Heartland Repack as "Senior Director of Operations for repacking." (SAC ¶ 8.) His responsibilities included overseeing repackaging, quality assurance, regulatory affairs, and wholesale and distribution—though at some point a reorganization removed wholesale and distribution from his supervision.

In mid-2004, Omnicare Senior Vice-President Denis Holmes suggested to relator that Heartland Repack consider adding amoxicillin and penicillin to the list of drugs repackaged at the facility. (*Id.* at ¶ 90.) Relator researched FDA guidelines and sent a memorandum to Holmes and to Omnicare's attorney Ralph Breitfeller. (*Id.* at ¶ 93.) The memorandum concluded that "repackaging penicillin alongside the other pharmaceuticals was in fact in violation of FDA regulations." (*Id*.) Because penicillin drugs can cause allergic reactions in up to two percent of patients, the FDCA current Good Manufacturing Practices ("CGMP") require that "[o]perations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use." 21 C.F.R. § 211.42(d).

During his research, relator contacted the manager for the Heartland Healthcare Services

pharmacy that continued to share the warehouse building with Heartland Repack. The pharmacy manager there advised him that the pharmacy "repacked penicillin frequently." (SAC ¶ 94.) This was a problem, relator states, because "the pharmacy unit was separated from the repackaging unit only by large overhead doors (similar to garage doors) which . . . were kept open approximately 25 percent of the time during business hours." (*Id.* at ¶ 65.) And, "the same ventilation and heating/cooling system was used throughout the building." (*Id*.)

Relator advised both Holmes and Breitfeller of the situation, but according to relator, nothing was done to the remedy the problem. As relator alleges, "Holmes did not respond to Relator's suggestions regarding legal methods in which Heartland Repack could repackage penicillin. After relator left Holmes' office, the issue of repackaging penicillin at Heartland Repack was not brought up again." (*Id*. at ¶ 108.) Relator resigned from Heartland Repack on or about February 28, 2006, allegedly as a result of "repeated disagreements with management over quality control issues," including the cross-contamination issue. (*Id*. at ¶ 109.)

C. FDA Warning Letter

According to the Second Amended Complaint, relator "caused and precipitated" an FDA investigation of Heartland Repack in mid-2006. (*Id*. at ¶ 115.) "Approximately four or five months after resigning from Heartland Repack," relator was travelling on business for a new company, and he used a pay phone from the Cleveland Hopkins airport in Ohio "to call the FDA Unit in Cincinnati and report Heartland Repack's improper repackaging practices." (*Id.* at ¶ 110.)

The FDA sent inspectors to the Toledo facility. According to relator, Heartland Repack

employees told inspectors that "'no penicillin was being repackaged in the Repackaging Division' – a statement that was misleading because it failed to disclose that penicillin was being repacked in the pharmacy located in the same building . . . ." (*Id.* at ¶ 111.) Relator again contacted the FDA and was interviewed by two FDA agents to whom he "described the specific details of the penicillin exposure at Heartland Repack's Toledo facility." (*Id*. at ¶ 113.)

When the FDA returned to the Heartland Repack building, it inspected the neighboring pharmacy as well. The result of the investigation was described in an FDA Warning Letter sent to Omnicare on January 11, 2007. According to the letter, the

> [FDA investigator] documented serious deviations from the Current Good Manufacturing Practice (CGMP) regulations . . . These deviations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) [21 U.S.C. § 351(a)2)(B)] of the Federal Food Drug and Cosmetic Act.

(Warning Letter 1, ECF No. 94-1).

The penicillin cross-contamination issue is the first and most prominent CGMP deviation cited in the letter. According to the letter:

> *Separate or defined areas or other control systems to prevent contamination or mixup are inadequate, and operations relating to the repacking of penicillin are not performed in facilities separate from those used for non-penicillin drug products for human use. [21 CFR § 211.42(c) and (d)]* Specifically, your firm, which repacks human drugs, shares a building with a pharmacy that packs beta-lactam antibiotics, including penicillins and cephalosporins. Your facility shares a common dock area, common receiving area, doorways, an overhead door near the maintenance room, cleaning equipment, and personnel with the pharmacy. The pharmacy uses the common area to receive beta-lactams. Sufficient controls have not been established to prevent the exposure of cephalosporin drug products and non-beta-lactam drug products to cross-contamination, either with penicillin drug products or with each other.

(*Id.* at 2 (emphasis in original).) Citing the above problems, the letter continues:

> *Non-penicillin drug products were not tested for the presence of penicillin, when a reasonable possibility existed that a non-penicillin drug product had been*

> *exposed to cross-contamination with penicillin. [21 CFR § 211.176]* Specifically, your firm has not tested any of the human drug products that have been repacked by your firm for the presence of penicillin. As pointed out . . . above, your firm does not have separate facilities nor do you have separate air handling systems for handling penicillin products.

(*Id.* at 4 (emphasis in original).)

The letter acknowledged that Omnicare had promised to take corrective actions, including quarantining all products under Heartland Repack Services' control, recalling all products still within their expiration date, initiating a penicillin sampling program, ceasing all distribution of products until testing was complete, and "permanently moving [the] drug repackaging operation to a new facility." (*Id.* at 8.)

Information about Omnicare and Heartland Repack's actions subsequent to the investigation were made available in Omnicare's 2006 10-K filing with the SEC. There, according to relator, Omnicare "briefly mentioned its testing and the presence of beta-lactam residue," (SAC ¶ 119), and the companies "wrote-off the inventory at a pretax cost of $18.9 million and disposed of the drugs." (*Id.* at ¶ 120.) According to information obtained from FDA enforcement reports, relator further concluded that the defendant had not, at the time of the second amended complaint, recalled any products due to penicillin contamination. (*Id*. at ¶ 121.) And, based on information and belief, relator alleges that the defendants "have not reimbursed the federal or state governments for any monies the governments improperly paid to Defendants or others for the adulterated, misbranded and ineligible pharmaceuticals." (*Id*.)

D. Procedural History

On May 15, 2007, relator filed the original complaint in this action as a *qui tam* litigant

on behalf of the United States and various states and cities. (ECF No. 1.) Pursuant to 31 U.S.C. §3730(b)(2), the original complaint was filed under seal to afford the United States time to consider whether to intervene. After several motions for extension of time filed by the United States on behalf of itself and the other parties, relator filed an amended complaint on February 9, 2009, also under seal. (ECF No. 23.) The United States eventually declined to intervene, but requested that the court solicit written consent of the United States before granting any settlement or dismissal. (ECF No. 29.) Similar notices to decline intervention were filed by the states of California, Florida, Illinois, Michigan, Nevada, New York, and Texas. On October 26, 2010, relator filed a second amended complaint, which was unsealed on November 9, 2010, and served upon defendants on November 19, 2010.

Relator's second amended complaint contains twenty-nine counts. The first three counts allege violations of the federal False Claims Act, and counts four through twenty-nine allege violations of parallel state and local acts. Count I alleges a violation of § 3729(a)(1) of the federal FCA, which provides for liability for any person who "knowingly presents, or causes to be presented, to [the government] a false or fraudulent claim for payment or approval." Count II alleges a violation of § 3729(a)(2), which similarly provides liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." And Count III alleges a violation of § 3729(a)(7), which provides for liability for a person who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government."[6]

[6] As noted below, Congress amended the language and numbering of §3729(a) in 2009. The references in the SAC are to the code prior to amendment.

On September 30, 2011, defendants filed a motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim. Relator filed a response, and the United States also filed a Statement of Interest. Defendants filed a reply. Subsequently, relator filed a motion for leave to file a surreply to defendants' reply to the United States's Statement of Interest, and defendants filed a response to the final motion. The motion for leave to file a surreply will be granted. *See* Local Rule 105.2(a). Below, the court addresses defendants' motion to dismiss.

II. DISCUSSION

A. Subject Matter Jurisdiction – Public Disclosure Bar

In a False Claims Act case, a relator bears the burden of showing that subject matter jurisdiction exists. *U.S. ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 347–48 (4th Cir. 2009). "Unless 'the jurisdictional facts are intertwined with the facts central to the merits of the dispute,' the district court may then go beyond the allegations of the complaint and resolve the jurisdictional facts in dispute by considering evidence outside the pleadings, such as affidavits." *Id.* at 348 (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982)). A court should grant a motion to dismiss for lack of subject matter jurisdiction "if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999).

As an initial matter, federal district courts have subject matter jurisdiction over all civil actions "arising under" the laws of the United States. 28 U.S.C. § 1331. "A suit 'arises under' federal law if federal law creates the cause of action." *Provident Life & Acc. Ins. Co. v. Waller*, 906 F.2d 985, 988 (4th Cir. 1990). Here relator's core claim is a violation of federal law, the

federal FCA, and therefore § 1331 applies, and the court therefore also has supplemental jurisdiction over the state law claims arising from the same transactions. *See* 28 U.S.C. § 1367; 31 U.S.C. § 3732(b).[7]

The False Claims Act, however, contains additional jurisdictional restrictions that "bar[] federal courts from exercising subject matter jurisdiction over certain *qui tam* actions." *United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.*, 528 F.3d 292, 299 (4th Cir. 2008) (citing *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007)), *rev'd on other grounds* by 130 S. Ct. 1396 (2010). Relevant here, language known as the "public disclosure bar" relieves courts of jurisdiction where a relator's claims have been publicly disclosed prior to the filing of the suit and the relator cannot establish that he is an "original source" of the information underlying the complaint. 31 U.S.C. § 3730(e)(4). Congress's purpose in enacting the public disclosure bar was to find "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *Wilson*, 528 F.3d at 306 (quoting *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994)).

Until the statutory language was amended in 2010, the public disclosure bar provided that:

> [n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative . . . report, hearing, audit, or investigation . . . unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

[7] Relator expressly alleges as much, (SAC ¶¶ 1–3), which makes defendants' objection that relator did not properly plead subject matter jurisdiction under § 1331 somewhat mystifying.

31 U.S.C. 3734(e)(4)(A) (2006).[8] The FCA thus requires the court "to answer three questions: Was there a public disclosure? If there was a public disclosure, was the *qui tam* action based on the public disclosure? If the action was based on the public disclosure, was the *qui tam* plaintiff an original source?" *Wilson*, 528 F.3d at 299. Defendants argue that this action is based on a public disclosure—the FDA warning letter—and that relator cannot establish that he is an "original source."

Relator does not contest defendants' argument that the FDA warning letter sent to Omnicare constitutes a public disclosure within the terms of the False Claims Act. Rather, relator argues that the complaint is not "based on" the warning letter, within the meaning of the term as interpreted by the Fourth Circuit, and that in any case relator is an original source of the information contained in the letter. On this latter point the court agrees, making moot the question of whether the complaint is "based upon" the warning letter.[9]

Section 3734(e)(4)(B) defines the term "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based and has

[8] Section 10104(j)(2) of the March 23, 2010, Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 ("PPACA") "replace[d] the prior version of 31 U.S.C. § 3730(e)(4) with new language." *Graham County Soil and Water Conserv. Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010). The legislation makes no reference to retroactivity, however, and thus does not apply to this case. *See Id*.

[9] It is appropriate here to skip consideration of whether the complaint is "based upon" the public disclosure because the Fourth Circuit's minority approach to this question, in practice, merges into the question of whether the relator is an "original source." The Fourth Circuit maintains the minority view that "a *qui tam* action is based upon publicly disclosed allegations *only* if the qui tam plaintiff's allegations were actually *derived from* the public disclosure itself." *Wilson*, 528 F.3d at 308 (emphasis in original) (citing *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1348 (4th Cir. 1994)). Under this approach, a claim is not "derived from" the public disclosure if relator "had independent knowledge of the facts and did not derive his allegations from the public disclosure itself." *Id.* As discussed below, "independent knowledge of the facts" is one of the statutory requirements for finding a relator to be an original source.

Of further note, in future cases the court will not need to consider this question, as PPACA amended § 3730(e)(4)(A) to eliminate the phrase "based upon." The public disclosure bar instead now requires original source status "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . ." 31 U.S.C.A. § 3730(e)(4)(A) (West 2012).

voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3734(e)(4)(B). Relator has provided detailed allegations sufficient to meet his burden of proving original source status.

First, relator has adequately alleged that he voluntarily provided information about the alleged fraud to the government before the initiation of this suit. Relator alleges that he "originally brought Heartland Repack's unlawful activities to the attention of the FDA," (SAC ¶ 116), by calling the FDA Unit in Cincinnati to "report Heartland Repack's improper repackaging practices." (*Id.* at ¶ 110.) And relator again voluntarily initiated contact with the FDA after he learned of the first unsuccessful inspection. (*Id.* at ¶ 112.) Thus, the inspection and audit leading to the FDA warning letter "were caused and precipitated by Relator." (*Id.* at ¶ 116.)

Defendants correctly argue that a relator is not necessarily an "original source" of a public disclosure simply because, as here, the relator voluntarily provided the tip that led to the government investigation and public disclosure. In other words, a relator does not become an original source "merely by communicating to the government, 'I think something fishy is going on in connection with Government Contract A and Contractor B,' and then relying on the evidence of fraud, if any, disclosed by a subsequent government investigation." *U.S. ex rel. Detrick v. Daniel F. Young, Inc.*, 909 F. Supp. 1010, 1022 (E.D. Va. 1995). Rather, the relator must have a "core of knowledge about the fraud" that is direct and independent of the subsequent government investigation. *Id*. at 1020; *see also United States v. New York Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (holding that a third party cannot be "'the source of the core information' upon which the *qui tam* complaint is based"); *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1163 (10th Cir. 1999) (finding no direct and

independent knowledge where "most of the core information contained in the complaint came from [a third party's] independent research and investigation and not from [the relator]").

Relator has, however, sufficiently alleged and shown that he possessed and communicated the "core" information that was later included in the warning letter. Relator alleged that he undertook independent research into the regulations regarding penicillin cross-contamination over two years before the FDA warning letter. (SAC ¶ 93.) He alleged that he learned independently of the penicillin repacking in the adjacent pharmacy at about the same time. (*Id.* at ¶ 94.) Relator alleged that, in his first call to the FDA, he reported Heartland Repack's "improper repackaging practices." (*Id.* at ¶ 110.) And, when relator later was interviewed by the FDA agents, he "described the specific details of the penicillin exposure at Heartland Repack's Toledo facility." (*Id.* at ¶ 113.)

The FDA investigation and warning letter—at least the portion of it cited in relator's complaint—does not add any significant new knowledge. Rather, the investigation only "verified that penicillin was, in fact, being repackaged in the same building as Heartland Repack" and confirmed that "[t]his was in violation of FDA guidelines and regulations." (*Id.* at ¶ 114.)[10] Defendants also note that both the warning letter and relator's complaint cite to the same section of the FDA regulations, but this can hardly be evidence that relator did not have independent knowledge. Indeed, relator alleges that his 2004 memorandum to his Omnicare supervisor "contained citations from the appropriate CGMP guidelines, as well as references to specific cases where the FDA fined and shut down facilities that were in violation of the

[10] The detail with which relator alleges he communicated his concerns about penicillin repackaging to both his supervisors and to the FDA distinguishes this case from *New York Medical College*, in which "Plaintiffs' amended complaint relie[d] overwhelmingly on the 'confirmed' and 'quantified' findings of HHC's two audits, rather than on plaintiffs' own 'unconfirmed' and 'unquantified' suspicions of fraud." 252 F.3d at 121.

regulations." (*Id.* at ¶ 93.) In any case, while relator must have independent knowledge of the "core" information underlying the action, it is not necessary that a relator have "independent knowledge of *everything* in his fraud complaint." *Detrick*, 909 F. Supp. at 1020 (emphasis added). To be an original source, relator need only have possessed and communicated the "'core of knowledge' . . . not a comprehensive whole." *U.S. ex rel. Ackley v. Int'l Bus. Machs. Corp.*, 76 F. Supp. 2d 654, 666 (D. Md. 1999) (quoting *Detrick*, 909 F. Supp. at 1020).

Defendant also argues that relator's claim fails the public disclosure bar because he does not have direct and independent knowledge of the actual, specific, claims for payment made to the government by Omnicare pharmacies and the facilities they served. This argument, however, skips an important step in the public disclosure bar analysis. The public disclosure at issue here—the FDA investigation and warning letter—does not contain information about alleged claims for payment. Thus, relator need not prove he is an "original source" of this missing information.

Furthermore, to survive the public disclosure bar, a relator need only demonstrate direct and independent knowledge of the facts to the extent that those facts are "necessary to plead a plausible fraud claim [under Rule 9(b)]." *U.S. ex rel. Davis v. Prince*, 753 F. Supp. 2d 569, 583 (E.D. Va. 2011) (citing *Vuyyuru*, 555 F.3d at 353). The Rule 9(b) pleading standard usually requires a showing in the complaint of *specific* claims for payment. *U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301, 1312 (11th Cir. 2002). However, this standard may be relaxed where a relator has adequately alleged the existence of a fraudulent scheme. *See, e.g., U.S. ex rel. DeCesare v. Americare In Home Nursing*, 757 F. Supp. 2d 573, 583 (E.D. Va. 2010 (finding a complaint survives Rule 9(b) where relator alleges a fraudulent

scheme that shows every certification is false even though he "does not point to a specific moment of fraud in terms of a time and date"). Here, as in *DeCesare*, relator has adequately alleged the existence of a fraudulent scheme under which *every* claim submitted by downstream pharmacies and long-term care facilities to the government for a drug product repacked at Heartland Repack was false.[11] Rule 9(b) therefore does not require relator here to have alleged knowledge of *specific* claims, and therefore neither does relator need to show direct and independent knowledge of such claims to meet the public disclosure bar.

In sum, assuming that the complaint is based upon publicly-disclosed information, relator has alleged sufficient facts to show by a preponderance of the evidence that he was an original source of this information. He has alleged the details of his prior knowledge with particularity, including the names of specific individuals who provided him with information about penicillin repacking and made decisions about whether to act on red flags, the manner in which the interactions between relator and the FDA were precipitated, and the names of the FDA agents who interviewed relator. As a result, the public disclosure bar does not apply, and the court has subject matter jurisdiction in this case.[12]

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[11] This fact, that *every* claim generated by Heartland Repack would be fraudulent under relator's theory, distinguishes this case from *United States v. Kernan Hospital*, --- F. Supp. 2d ----, 2012 WL 3088210 (D. Md. July 30, 2012), in which another judge in this district recently dismissed a Medicare reimbursement-related FCA complaint for failure to adequately plead fraud under Fed. R. Civ. P. 9(b).

[12] In finding subject matter jurisdiction, the court has also considered and found unavailing defendants' argument that relator's failure to allege satisfaction of the Act's procedural requirements is a jurisdictional bar. As defendant notes, the SAC does not specifically allege that relator has provided the United States with a "copy of the complaint and written disclosure of substantially all material evidence and information [the relator] possesses," as is required by § 3730(b) of the FCA. Defendants have not provided the court with any caselaw holding that the procedural requirements of § 3730(b) are jurisdictional, but in any case there is no material dispute at this stage in the litigation as to whether the relator in fact *made* the required disclosures. The only relevant evidence in the record consists of the various seal-extension motions and notices of non-intervention filed by the United States and the other plaintiffs. These filings indicate that governmental entities had notice of the complaint, and none mention any procedural failures. At this point, therefore, even if the procedural requirements of § 3730(b) are jurisdictional, they do not represent a bar to subject matter jurisdiction in this case.

B. 12(b)(6) Failure to State a Claim

Nonetheless, having assumed jurisdiction, the court must dismiss relator's suit pursuant to Fed R. Civ. P. 12(b)(6). A Rule 12(b)(6) motion tests the sufficiency of a complaint and does not "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006) (internal quotation marks and alterations omitted) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)). When ruling on such a motion, the court must "accept the well-pled allegations of the complaint as true" and "construe the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff." *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). However, the court "need not accept the legal conclusions drawn from the facts, and [] need not accept as true unwarranted inferences, unreasonable conclusions or arguments." *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009).

To survive a motion to dismiss, the factual allegations of a complaint, assumed to be true, "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The plaintiff's obligation is to *show* sufficiently the "grounds of his entitlement to relief," offering "more than labels and conclusions." *Id.* It is not sufficient that the well-pleaded facts suggest "the mere possibility of misconduct." *Ashcroft v. Iqbal*, --- U.S. ---, 129 S. Ct. 1937, 1950 (2009). Rather, to withstand a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," meaning the court could draw "the reasonable inference that the defendant is liable for the conduct alleged." *Id*. at 1949 (internal quotations and citation omitted).

The False Claims Act allows private "*qui tam*" litigants to bring actions on behalf of the

government against anyone who, in the language of the statute prior to its amendment in 2009,

> (1) knowingly presents, or causes to be presented, to [the government] a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]
>
> . . .
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, ...

31 U.S.C. § 3729(a) (2006)[13]; *see id.* § 3730(b). For the purposes of this section, "'knowing' and 'knowingly' mean that a person, with respect to information- (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) (citing 31 U.S.C. § 3729(b)).

"Liability under each of the provisions of the False Claims Act is subject to the further, judicially-imposed, requirement that the false statement or claim be material." *Harrison*, 176 F.3d at 785. "Materiality depends on 'whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action.'" *Id.* (quoting *United States ex rel. Berge v. Bd. of Trs. of Univ. of Ala.*, 104 F.3d 1453, 1459 (4th Cir. 1997)). "Materiality is

[13] On May 20, 2009, Congress amended the FCA by passing the Fraud Enforcement and Recovery Act of 2009 (FERA), PL 111-21, 123 Stat 1617. FERA changed the numbering of 31 U.S.C. § 3729(a) and also changed the language of the statute to include an express materiality requirement for the false record provisions in § 3729(a)(2) and to change the definition of "obligation" in § 3729(a)(7). The courts that have addressed the question of retroactivity have overwhelmingly concluded that the FERA amendments are only retroactive for *claims* (not cases) pending on June 7, 2008. *See United States v. Kernan Hospital*, --- F. Supp. 2d ----, 2012 WL 3088210, at **7–8 (D. Md. July 30, 2012) (listing cases regarding § 3729(a)(2)); *U.S. ex rel. Bahrani v. ConAgra, Inc.*, 624 F.3d 1275, 1303 n.14 (10th Cir. 2010) (holding that FERA was not retroactive as to § 3729(a)(7)). As a result, the court will apply the pre-FERA version of the FCA in this case, as relator has alleged no claims pending subsequent to the date the original complaint was filed in 2007.

a mixed question of law and fact." *Id.*

Thus, for all three of the statutory provisions under which Rostholder alleges liability, the test for False Claims Act liability includes four prongs: "(1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a "claim")." *Id.* at 788 (discussing § 3729(a)(1) and § 3729(a)(2)); *see U.S. ex rel. Sanders v. N. Am. Bus Indus., Inc.*, 546 F.3d 288, 297, 299 (4th Cir. 2008) (applying the same test to a claim under 31 U.S.C. § 3729(a)(7) as well).[14]

Rostholder has not convinced the court that this case meets the first prong of this test under the existing law in the Fourth Circuit. "To satisfy this first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376–377 (4th Cir. 2008) (citations omitted). "As a result, mere 'allegations of poor and inefficient management of contractual duties' are 'not actionable under the [FCA].'" *Id.* at 377 (citing *Harrison*, 176 F.3d at 789). "Likewise, 'imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA.'" *Id.* (quoting *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)). "*Harrison []* makes clear that 'fraud may only be found in expressions of fact which (1) admit of being adjudged true or false in a way that (2) admit of empirical verification.'" *Id.* at 377–78 (quoting *Harrison*, 176 F.3d at 792 (internal quotations omitted)).

"In the paradigmatic case, a claim is false because it 'involves an incorrect description of

[14] "[T]here is no requirement that the government have suffered damages as a result of the fraud." *Id.* at 785 n.7 (citing *U.S. ex rel. Joslin v. Cmty. Home Health of Maryland, Inc.*, 984 F. Supp. 374, 383 (D. Md. 1997)).

goods or services provided or a request for reimbursement for goods or services never provided.'" *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010) (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)). A claim may also be fraudulent where invoices submitted to the government falsely inflate the actual cost of providing goods or services. *See United States v. Rachel*, 289 F. Supp. 2d 688, 697 (D. Md. 2003); *see also U.S. ex rel. DRC, Inc. v. Custer Battles, LLC*, 562 F.3d 295, 299, 305 (4th Cir. 2009) (suggesting invoices billing the Coalition Provisional Authority in Iraq for substantially more than the actual cost of goods provided are actionable as fraudulent claims under the FCA). And, a claim may be fraudulent where the defendant "misrepresents the quality of a product in an effort to achieve an unwarranted payment for inferior goods." *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 346 (4th Cir. 2010).[15]

Similarly, under the "false certification" doctrine, "[w]here the Government conditions payment of a claim upon certification of compliance with a statute or regulation, . . . a party violates the FCA by falsely certifying compliance with the statute or regulation." *U.S. ex rel. Joslin v. Cmty. Home Health of Maryland, Inc.*, 984 F. Supp. 374, 383–84 (D. Md. 1997) (citations omitted).[16] Courts have generally declined to "find liability *merely* for non-compliance with a statute or regulation." *Harrison*, 176 F.3d at 786–87 (emphasis added). But, a claim for payment may be false within the bounds of the FCA when the claim "rests on a false

[15] As discussed below, a variant of this paradigmatic case is the "worthless services" claim, where a product or service provided is "so deficient that for all practical purposes it is the equivalent of no performance at all." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (quoting *Mikes v. Straus*, 274 F.3d 687, 702–03 (2d Cir. 2001)).

[16] Some courts have describes false certification claims as claims of "legal" falsity, as opposed to the "paradigmatic" claims describes above, which are claims of "factual" falsity. *See, e.g., U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citing *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). *But see U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 385–86 (1st Cir. 2011) (declining to employ the factual/legal distinction because it has no basis in the text of the FCA statute and "may do more to obscure than clarify the issues before us").

representation of compliance with an applicable federal statute, federal regulation, or contractual term," *Sci. Applications*, 626 F.3d at 1266, and where compliance is a "prerequisite" to payment of the claim by the government. *Harrison*, 176 F.3d at 786.[17] Thus, for example, when a Medicare or Medicaid-reimbursed provider falsely certifies its compliance with the Anti-Kickback Statute limiting payments as inducements for health care referrals, claims for government reimbursement submitted pursuant to that certification may be considered false or fraudulent within the meaning of the FCA. *DeCesare*, 757 F. Supp. 2d at 586–87.

A majority of the circuits have now extended the certification doctrine to apply also to implied—as well as express—false certifications. *See Mikes*, 274 F.3d at 700; *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 306 (3d Cir. 2011); *U.S. ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415–16 (6th Cir. 2002); *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 996–98 (9th Cir. 2010); *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *Sci. Applications*, 626 F.3d at 1266, 1270–71; *see also McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259–60 (11th Cir. 2005) (agreeing that liability may attach to claims where defendant violated the Anti-Kickback Statute, though not discussing the term "implied false certification"). *Cf. U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385–88 (1st Cir. 2011) (declining to adopt the terminology of "certification," but favorably citing the D.C. Circuit's approach in *SAIC* for determining whether a claim is false or fraudulent).

[17] As the Fourth Circuit mentioned in *Harrison*, the legislative history of the act supports the conclusion that statutory and regulatory violations may, at least in some way, produce a "false claim:"

> [E]ach and every claim submitted under a contract, loan guarantee, or other agreement *which was originally obtained* by means of false statements or other corrupt or fraudulent conduct, *or in violation of any statute or applicable regulation*, constitutes a false claim.

Harrison, 176 F.3d at 786 (emphasis in original) (quoting S. Rep. No. 99-345, at 9, reprinted in 1986 U.S.C.C.A.N. at 5274).

The Fourth Circuit, however, has not yet adopted the implied certification doctrine, and relator clarified at oral argument that he does not ask the court to do so. Indeed, relator explained that this is not a false certification case at all, express or implied. Relator argues instead that the court need only apply the "traditional materiality" test of the Fourth Circuit, directing the court's attention to *Harrison*. Relator thus appears to argue that any claim for goods or services provided in violation of a statute or regulation represents "fraudulent conduct" within the meaning of *Harrison*—as long as the violation is material. In other words, the court need not analyze whether "fraudulent conduct" exists separately from the materiality prong of the test.

Harrison, however, suggests materiality and fraudulent conduct are separate prongs of the test. The court held that liability under the FCA is "subject to the *further*, judicially-imposed, requirement that the false statement or claim be material." 176 F.3d at 785 (emphasis added). Thus where a false certification of regulatory compliance is given—satisfying the false statement or fraudulent conduct prong—the relator must *also* prove materiality. In a case like this, where no facially false statement is given, other circuits might apply an implied certification doctrine to address the first prong of the test. *Harrison* suggests the appropriate alternative in the Fourth Circuit is to apply a traditional analysis of fraud by omission. *Id.* at 787 n.8 (citing *Berge*, 104 F.3d at 1461).

The *Berge* decision cited in *Harrison* held that while an omission may render an otherwise truthful statement or claim false or fraudulent, ""[t]here can only be liability under the False Claims Act where the defendant has an obligation to disclose the omitted information." *Berge*, 104 F.3d at 1461 (citing *United States ex rel. Milam v. Regents of the Univ. of Cal.*, 912

F. Supp. 868, 883 (D. Md. 1995)); *see also U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 915–16 (4th Cir. 2003) ("*Harrison II*") (distinguishing *Harrison* from *Berge*). In other words, the nondisclosure of regulatory violations alone does not automatically equate to "fraudulent conduct." *See Mann*, 630 F.3d at 346 ("Correcting regulatory problems may be a laudable goal, but one not actionable under the FCA *in the absence of actual fraudulent conduct*." (emphasis added) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996))). It is the omission of the fact that a regulatory violation occurred—where an obligation to disclose that fact existed—that is "fraudulent" for the purposes of the FCA.[18] Relator did not address fraud by omission or identify any obligation to disclose in his briefing or at oral argument.

In sum, relator does not argue there was an affirmative false statement or false certification; relator does not argue this court should adopt the implied certification theory; and relator does not argue for the theory of fraud by omission, which *Harrison* appears to suggest may be appropriate under some circumstances. Relator's argument instead appears to read the first prong—false statement or fraudulent conduct—out of the *Harrison* test for FCA liability. Without clearer guidance from the Fourth Circuit, I cannot agree that such an approach is appropriate as to claims brought here under 31 U.S.C.A. § 3729(a)(1), § 3729(a)(2), and § 3729(a)(7), as relator has alleged them.

Moreover, also relevant to the 12(b)(6) analysis is relator's failure to provide sufficient

[18] In addition, "[a]t common law, fraud has not been limited to those situations where there is an affirmative misrepresentation or the violation of some independently-prescribed legal duty," *United States v. Colton*, 231 F.3d 890, 898 (4th Cir. 2000), such as the obligation to disclose discussed in *Harrison* and *Berge*. "Rather, even in the absence of a fiduciary, statutory, or other independent legal duty to disclose material information, common-law fraud includes acts taken to conceal, create a false impression, mislead, or otherwise deceive in order to 'prevent[ ] the other [party] from acquiring material information.'" *Colton*, 231 F.3d at 898 (quoting Restatement (Second) of Torts § 550 (1977)). Relator does not, however, allege any active concealment or suppression on the part of Omnicare. He alleges only the failure to disclose.

specificity as to the content of the claims allegedly made by downstream actors. The False Claims Act "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the *claim* for payment." *Harrison*, 176 F.3d at 785 (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)). Presumably, the actual "claims" in this case are the reimbursement requests and reports sent by Omnicare pharmacies, SNFs and other intermediaries to CMS. Relator, however, has not sufficiently explained the nature of this process or directed the court to the specific regulations, guidance manuals, or specific forms that are used in the payment process—much less copies of the specific forms that requested reimbursement for the Heartland Repack drugs at issue. *Compare DeCesare*, 757 F. Supp. 2d at 577–78 (allowing Medicare-related FCA claims to proceed where relator provided language from and specific regulations requiring annual provider cost reports), *with United States v. Kernan Hospital*, --- F. Supp. 2d ----, 2012 WL 3088210, at *10 (D. Md. July 30, 2012) (dismissing healthcare reimbursement claims where relator did not include copies of cost reports or "even explain the circumstances under which such reports are submitted"). Indeed, relator's complaint is at times frustratingly unspecific. For example, in the Second Amended Complaint, relator described Medicare Part C in the following manner:

> To the extent the law required the Part C Providers to provide the government with pricing and other data concerning these prescriptions to ensure that Medicare ultimately only paid for the actual cost of FDA approved drugs dispensed, then Defendants' conduct rendering the drugs ineligible for payment concomitantly rendered the data submitted to justify their coverage false and/or fraudulent.

(SAC ¶ 82.) Relator cites no specific regulation that requires the pricing data, and does not in fact appear to plead with certainty that such a requirement even exists.

Relator asks too much of the court. Given no specific claim pleaded, no names of

specific downstream actors who submitted the alleged claims, no specific forms or processes of claims adequately described, and no theory of fraudulent conduct other than "materiality," the court simply cannot determine that this FCA case has been adequately alleged under Fourth Circuit precedent. As a result, the court must grant defendants' motion to dismiss under Fed. R. Civ. P. 12(b)(6).[19]

CONCLUSION

For the above reasons, the court will grant defendants' motion to dismiss for failure to state a claim. Because relator has already filed a Second Amended Complaint, this dismissal will be with prejudice as to relator and any further leave to amend will not be granted.

The government has requested that any dismissal of relator's claim should be without prejudice as against the United States, and the court agrees. The government's decision not to intervene in this case does not suggest that the government necessarily believed that no FCA case was viable. As the Fourth Circuit has noted, a decision not to intervene may "not [necessarily be] an admission by the United States that it has suffered no injury in fact, but rather [the result of] a cost-benefit analysis." *Berge*, 104 F.3d at 1458; *see also Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005) (holding that dismissal with prejudice as to the United States was improper where basis for dismissal was failure to meet heightened pleading standard under FRCP 9(b)). Accordingly, it would be inappropriate to dismiss with

[19] This opinion should not be taken to suggest that a violation of the CGMP may never result in FCA liability. The government, in its Statement of Interest, submits that "violations of CGMP regulations may, in certain circumstances, be material to the government's decision whether to pay for the affected products, and thus relevant in an FCA case." (Statement of Interest 4, ECF No. 89.) As an example, the government directs the court's attention to the "worthless services" doctrine, under which "the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all." *Mikes*, 274 F.3d at 703. As with the implied certification doctrine, relator has specifically declined to address the worthless services doctrine in this case and the court therefore will not consider it.

prejudice as to the United States or as to the states or localities on whose behalf relator brought this claim.

A separate order follows.

August 14, 2012
Date

/s/
Catherine C. Blake
United States District Judge